#### **APPLICATION**

of

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for

#### UNITED STATES LETTERS PATENT

on

#### AMPLIFIER SYSTEM FOR DETERMINING PARAMETERS OF A PATIENT

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#### AMPLIFIED SYSTEM FOR DETERMINING PARAMETERS OF A PATIENT

This invention relates to a system for amplifying signals from electrodes attached to a patient's skin without any loss in signal strength and without any change in signal characteristics.

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#### **BACKGROUND OF THE INVENTION**

Measurements are provided in a patient of the functioning of various organs in a patient's body. For example, measurements are made of the functioning of the patient's heart, the patient's brain and the patient's stomach and intestinal tract. These measurements are generally made by applying an electrode to the skin of the patient at the appropriate position or positions on the patient's body.

The measurements of the functioning of different organs in the patient's body involve different frequency ranges. For example, measurements of the patient's heart occur in a range of DC to approximately two hundred and fifty hertz (250 Hz); measurements of the patient's brain occur in a range of DC to approximately one hundred and fifty hertz (150 Hz); and measurements of the functioning of the patient's stomach and intestinal tract occur in a range of DC to approximately one hertz (1 Hz).

The measurement of the functioning of different organs in the patient's body involve signals of miniscule amplitude. For example, the range of voltages produced at an electrode attached to the patient's skin for a measurement of the patient's heart is in a range of approximately one half of a millivolt (0.5 mV) to approximately four millivolts (4 mV); a range of voltages produced at an electrode attached to the patient's skin for a measurement of the patient's brain is in a range of approximately five microvolts (5  $\mu$ V) to approximately three hundred microvolts (300  $\mu$ V); and a range of voltages for the functioning of the patient's stomach and

intestines is in a range of approximately ten microvolts (10  $\mu$ V) to approximately one thousand microvolts (1000  $\mu$ V).

When an electrode is attached to a patient's skin to measure the functioning of an organ such as the patient's brain, heart or stomach or intestinal tract, the voltage generated from the organ has to penetrate from the organ through the patient's skin to the electrode. This is probably one reason why the voltage produced at the electrode is in the range of millivolts from the heart and in the range of microvolts from the brain and the stomach and intestinal tract.

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The skin has many layers. The greater the number of layers that the voltage has to penetrate in the patient's skin, the greater is the impedance that the skin presents to the voltage generated by the organ whose function is being measured. The problem of high impedances is compounded if the patient's skin is not clean when the measurement is being made. Thus, the impedance presented by the patient's skin may vary from a low impedance to an impedance of approximately two hundred thousand (200,000) ohms.

In view of the different parameters (e.g. signal frequency, voltage range and skin impedance) provided for measurements of different organs in a patient's body, special instruments have been provided to measure the functions of the different organs in the patient's body. For example, instruments for measuring the functioning of a patient's heart are not used to measure the functioning of a patient's brain or a patient's stomach or intestinal tract. Separate instruments have been used to measure the functioning of different organs in a patient's body even though the need or at least the desirability of providing a universal instrument capable of measuring the functioning of different organs in the patient's body has been recognized for some time.

Applicant filed application 10/293,105 (attorney's file RECOM-61830) in the U.S. PTO on 11/13/02 for a System For, and Method of, Acquiring Physiological Signals of a Patient and has assigned this application 10/293,105 to the assignee of record of this application. Application 10/293,105 discloses and claims a system including a plurality of channels each of which has properties of

producing signals indicating the functionality of any one of a number of different organs in a patient's body. As disclosed in application 10/293,105, each channel is adapted to be coupled to any one of a number of organs in the patient's body. Each channel includes an amplifier which is operable to produce signals representing the functionality of any one of the organs to which the channel is coupled.

## BRIEF DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

This invention provides an amplifier system which provides an amplification of the signals from any one of a plurality of organs in a patient's body regardless of the organ to which the amplifier system is coupled. The amplifier system includes an amplifier which is operative to amplify the signals from any selected one of the organs in the patient's body without any loss in the signal strength and without any changes in the characteristics of the signals.

In accordance with a preferred embodiment of the invention, an electrode is attached at a selective position to a patent's body to provide signals representative of the patient's parameters (e.g., electrocardiogram) at this position. The electrode signal may be in the order of microvolts or millivolts. Depending upon the characteristics of the patient's skin, the electrode-skin impedances may vary to approximately 200 kilohms. The electrode signals pass to an amplifier having an input impedance (e.g., 10<sup>15</sup> ohms) approaching infinity and a low output impedance (e.g. 50 ohms). The amplifier impedances ensure that the electrode signal will pass through the amplifier without loss in signal strength and change in signal characteristics. A low pass filter connected to the amplifier input eliminates noise and passes signals at low frequencies (e.g., 1 kilohertz maximum).

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#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a circuit diagram, substantially in block form, of an amplifier system, including a pair of amplifiers and a pair of electrodes, constituting a preferred embodiment of the invention;

Figure 2 is a circuit diagram of one of the amplifiers included in the amplifier system shown in Figure 1;

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Figure 3 is a schematic perspective view of the different layers in a patient's skin;

Figure 4 is a simplified elevational view of an electrode, a patient's skin (on a simplified basis) and a gel for facilitating the coupling between the electrode and the patient's skin and also shows the impedance network formed by the electrode, the gel and the patient's skin;

Figure 5 is a schematic perspective view showing the attachment of an electrode in Figure 1 to a patient's skin to provide signals from organs (e.g., heart) in the patient's body for introduction to the amplifier system also shown in Figures 1 and 2; and

Figure 6 is a circuit diagram, substantially in block form, of a system modified from that shown in Figure 1.

# DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT OF THE INVENTION

Figure 3 is a schematic perspective view of the different layers in a patient's skin. As will be seen, there are a number of layers in the patient's skin. The indications on the left of the figure represent groupings of layers. These groupings of layers are respectively designated as epidermis, dermis and subcutaneous. They include layers designated as stratum corneum, barrier, stratum granulosum, stratum germinativum and papillae.

Each of the layers in Figure 3 has an impedance. This is shown on a schematic basis in Figure 4, which shows an electrode, a gel, the epidermis layer and a combination of the dermis and subcutaneous layers. In Figure 4, the gel is shown as being disposed between the electrode and the epidermis to facilitate the coupling of the electrode to the epidermis layer with a minimal impedance.

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Figure 5 is a schematic view showing the attachment of an electrode 12 in Figure 1 to a patient's skin 11 to provide signals for introduction to the amplifier system also shown in Figure 1. A gel 13 may be disposed between the electrode 10 and the patient's skin 11 to facilitate the attachment of the electrode to the patient's skin. Since each of the layers has an impedance, the collective impedance of the patient's skin is progressively reduced when the successive layers are removed. With all of the layers in place on the patient's skin, the impedance of the patient's skin may be in the order of approximately two hundred thousand (200,000) ohms. However, the amplifier system in Figure 1 is constructed to operate satisfactorily even when successive layers are not removed from the patient's skin 11 and the electrode 10 is attached to the outside layer.

Figure 1 is a circuit diagram, primarily in block form, of an amplifier system, generally indicated at 10, constituting a preferred embodiment of the invention. The amplifier system 10 includes a pair of electrodes 12 and 14 each of which is suitably attached to skin at a selective position on the patient's body. The electrodes 12 and 14 preferably have an identical construction. The electrode 12 is positioned at a selective position on the skin of the patient's body to produce signals related to the functioning characteristics of an organ in the patient's body. The organ may illustratively be the patient's heart, brain or the patient's stomach or intestines. The electrode 14 is positioned on the skin of the patient's body at a position displaced from the selective position to provide reference signals. The difference between the signals at the electrodes 12 and 14 represents the functioning characteristics of the selected one of the patient's organs.

The signals on the electrode 12 are introduced to an input terminal of an amplifier generally indicated at 16. The amplifier 16 also has a second input

terminal which is connected to the output of the amplifier. In this way, the amplifier acts as a unity gain. The amplifier 16 may be purchased as an OPA 129 amplifier from the Burr-Brown Company which is located in Phoenix, Arizona. In like manner, the signals from the electrode 14 are introduced to an input terminal of an amplifier, generally indicated at 18, which may be identical to the amplifier 16. The amplifier 18 has an input terminal which is connected to the output terminal of the amplifier to have the amplifier act as a unity gain.

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Resistors 20 and 22 respectively extend from the output terminals of the amplifiers 16 and 18. The resistor 20 is connected to first terminals of capacitors 24 and 26. The second terminal of the capacitor 24 receives a reference potential such as ground. A connection is made from the resistor 22 to the second terminal of the capacitor 26 and to a first terminal of a capacitor 30, the second terminal of which is provided with the reference potential such as ground. The resistors 20 and 22 may have equal values and the capacitors 24 and 30 may also have equal values.

One terminal of a resistor 32 is connected to the terminal common to the capacitors 24 and 26. The other terminal of the resistor 32 has a common connection with a first input terminal of an amplifier 34. In like manner, a resistor 36 having a value equal to that of the resistor 32 is connected at one end to the terminal common to the capacitors 26 and 30 and at the other end to a second input terminal of the amplifier 34.

Since the amplifiers 16 and 18 have identical constructions, they operate to provide signals which represent the difference between the signals on the electrodes 12 and 14. This indicates the functioning of the patient's organ which is being determined by the amplifier system 30. Although the electrodes 12 and 14 are displaced from each other on the skin of the patient's body, they tend to receive the same noise signals. As a result, the difference between the signals on the output terminals of the amplifiers 16 and 18 does not include any noise.

The electrodes 12 and 14 respectively provide an impedance of approximately 10<sup>6</sup> ohms to the amplifiers 16 and 18. Each of the amplifiers 16 and 18 respectively provides an input impedance of approximately 10<sup>15</sup> ohms. This

impedance is so large that it may be considered to approach infinity. This causes each of the amplifiers 16 and 18 to operate as if it has an open circuit at its input. The output impedance of each of the amplifiers 16 and 18 is approximately 50 ohms to 75 ohms.

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Because of the effective open circuit at the input of each of the amplifiers 16 and 18, the output signal from each of the amplifiers 16 and 18 corresponds to the input signal to the amplifiers and does not have any less magnitude compared to the amplitude of the input signal to the amplifier. This is important in view of the production of signals in the microvolt or millivolt region in the electrodes 12 and 14.

The capacitors 24, 26 and 30 and the resistors 20 and 22 provide a low-pass filter and a differential circuit and operate to eliminate the noise on the electrodes 12 and 14. The capacitors 24, 26 and 30 also operate to provide signals which eliminate the commonality between the signals in the electrodes 12 and 14 so that only the signals individual to the functionality being determined relative to the selected organ in the patient's body remain. The capacitors 24, 26 and 30 operate as a low pass filter and pass signals in a range to approximately one kilohertz (1 KHz). The signals having a frequency above approximately one kilohertz (1 KHz) are atentuated.

The amplifiers 16 and 18 are identical. Because of this, a description of the construction and operation of the amplifier 16 will apply equally as well to the amplifier 18. The amplifier 16 is shown in detail in Figure 2. It is manufactured and sold by Burr-Brown in Phoenix, Arizona and is designated by Burr-Brown as the OPA 129 amplifier.

As shown in Figure 2, the amplifier 16 includes an input terminal 50 which receives the signals at the electrode 12 and introduces these signals to the gate of a transistor 52. The source of the transmitter 52 receives a positive voltage from a terminal 56 through a resistor 54. The emitter of the transistor 52 is common with an input terminal in a noise free cascode 58.

Another terminal 60 receives the signals on the electrode 14 and introduces those signals to a gate of a transistor 64. A connection is made from the source of the transistor 64 to one terminal of a resistor 66, the other terminal of which receives the voltage from the terminal 56. The emitter of the transistor 64 is common with an input terminal in the noise-free cascode 58. The resistor 66 has a value equal to that of the resistor 54 and the transistors 52 and 64 have identical characteristics.

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First terminals of resistors 68 and 70 having equal values are respectively connected to output terminals in the noise-free cascode 58 and input terminals of an amplifier 74. The amplifier 74 provides an output at a terminal 76. The output from the terminal 76 is introduced to the input terminal 60. The amplifier receives the positive voltage on the terminal 56 and a negative voltage on a terminal 78. Connections are made to the terminal 78 from the second terminals of the resistors 68 and 70.

The transistors 52 and 64 operate on a differential basis to provide an input impedance of approximately 10<sup>15</sup> ohms between the gates of the transistors. The output impedance from the amplifier 16 is approximately fifty (50) ohms to seventy-five (75) ohms. Because of the high input impedance of approximately 10<sup>15</sup> ohms, the amplifier 16 provides an input impedance approaching infinity. This causes the amplifier 16 to provide the equivalent of an open circuit at its input. This causes substantially all of the voltage applied to the input terminal 50 to be provided at the output of the amplifier 16. This is facilitated by the low impedance of approximately fifty ohms (50 ohms) to seventy-five (75) ohms at the output of the amplifier 12. This voltage has characteristics corresponding to the characteristics of the voltage at the electrode 12.

The output signals from the amplifiers 16 and 18 are respectively introduced to the terminal common to the capacitors 24 and 26 and to the terminal common to the capacitors 26 and 30. The capacitors 24, 26 and 30 operate as a low-pass filter to remove noise and to provide an output signal representing the difference between the signals on the electrodes 12 and 14.

The capacitors 24, 26 and 30 correspond to the capacitors C2, C1 and C3 in a low pass filter 76 in application 10/293,105 (attorney's file RECOM-61830) filed on 11/13/02 in the USPTO and assigned of record to the assignee of record in this application. The capacitors C2, C1 and C3 in application 10/293, 105 are included in the low pass filter 76 in Figure 8-1 (also shown in Figure 4) of such application. The low pass filter 76 eliminates noise and passes signals through a frequency range to approximately one kilohertz (1 KHz). If any further information may be needed concerning the construction and operation of the low pass filter, reference may be made to co-pending application 10/293,105 to obtain this information.

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Figure 6 shows a preferred embodiment, generally indicated at 81, constituting a modification of the amplifier system 10 shown in Figure 1. It is identical to the amplifier system 10 shown in Figure 1 except that it includes capacitors 82, 84 and 86 respectively corresponding to the capacitors 24, 26 and 30 also shown in Figure 1. The capacitors 82, 84 and 86 are connected as a low pass filter at the inputs of the amplifiers 16 and 18. Like the capacitors 24, 26 and 30, the capacitors 82, 84 and 86 operate as a low pass filter. The addition of the capacitors 82, 84 and 86 provides certain advantages. For example, it assures that no noise passes through the amplifier system 80. Furthermore, it assures that the amplifier system 80 provides stable output signals even when the amplifier system is included in an ambulatory system for measuring the heart characteristics of a patient.

Although this invention has been disclosed and illustrated with reference to particular embodiments, the principles involved are susceptible for use in numerous other embodiments which will be apparent to persons of ordinary skill in the art. The invention is, therefore, to be limited only as indicated by the scope of the appended claims.